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U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

U.S. GEOLOGICAL SURVEY

AT

DENVER, COLORADO

AUDIT NUMBER USGS-ARC-99-07

MARCH 22 THROUGH 25, 1999

Prepared by: _____ **Date:** _____
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Approved by: _____ **Date:** _____
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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit USGS-ARC-99-07, the audit team determined that the U.S. Geological Survey (USGS) is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8 and USGS implementing procedures for QA Program Elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 12.0, 15,0, 16.0, 17.0, Supplements I, II, and III, and Appendix C.

During the course of the audit, the audit team identified a total of eight conditions adverse to quality. One of these conditions resulted in the issuance of one new OCRWM Deficiency Report (DR), USGS-99-D-039, to address the improper processing of privileged records. Two other conditions were referred to previously issued open OCRWM deficiency documents. Corrective Action Request (CAR), USGS-98-C-004, identified position descriptions that failed to meet the requirements for education, experience and/or training. DR LVMO-98-D-055 identified that the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) failed to establish measures to identify and describe activities for determining controls for the Electronic Management of Data and the administration of the data without a procedure in place. The remaining five conditions adverse to quality identified by the audit team required remedial action only and were corrected prior to the post-audit meeting. These deficiencies are detailed in Section 5.5 of the Audit Report. Additionally, there were nine recommendations, which are described in Section 6.0 of this report.

USGS Good Practice

As part of the corrective action on previously issued DR, USGS-98-D-116, USGS committed that all scientific notebooks would be reviewed to a standard checklist reflecting the procedural requirements. A good practice at USGS is the completion of a checklist for each scientific notebook and making the checklist a part of the notebook. Hence, the formal review, the response, and the resolution of comments become an integral part of the scientific notebook.

2.0 SCOPE

The audit was conducted to evaluate the adequacy of the compliance and the effectiveness of the OCRWM QA Program as described in the QARD and USGS implementing procedures.

The following QA Program elements/requirements were evaluated during the audit, in accordance with the approved audit plan:

QA PROGRAM ELEMENTS

1.0	Organization
2.0	Quality Assurance Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of Electronic Management of Data
Appendix C	Mined Geologic Disposal System

The following QA Program elements were not evaluated, since the USGS currently has no activities to which these elements apply:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test, and Operating Status
18.0	Audits
Supplement IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

Name/Title/Organization	QA Program Element
Donald J. Harris, Audit Team Leader, OQA	4.0, 7.0, 12.0, Appendix C
Kenneth O. Gilkerson, Auditor, OQA	5.0, 6.0, Supplements I and V
Edward P. Opelski, Auditor, OQA	1.0, 2.0
Sam H. Horton, Auditor, OQA	15.0,17.0, Supplement II, Appendix C
James Blaylock, Auditor, OQA	16.0, Supplement III

No Observers were present at this Audit.

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

Prior to initiation of the formal audit, on March 18, 1999, members of the audit team visited the Yucca Mountain Site to gather information concerning field implementation of selected quality program elements to be evaluated during the audit. The pre-audit meeting was held on March 22, 1999, at USGS offices in Denver, Colorado. Daily debriefing and coordination meetings were held with USGS management and staff, and daily audit team meetings were held to discuss audit status. The audit was concluded with a post-audit meeting on March 25, 1999, at USGS offices located in Denver, Colorado. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment I of this report.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, USGS implementation of the QA Program is adequate and is being satisfactorily implemented for the scope of the audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results for Procedural Compliance Evaluations.

In addition to the summary in Attachment 2, audit observations were noted and summarized as Recommendations in Section 6.0 below. Although implementation of QA Program Element 2.0 was determined to be acceptable overall, it should be noted that USGS Management is actively assessing deficient conditions associated with the qualifications of USGS and contractor personnel to formulate necessary corrective actions. This audit confirmed an additional example of this problem which was previously identified in CAR, USGS-98-C-004. This is discussed in detail in Section 5.5.1.

As part of the corrective action on DR USGS-98-D-116, USGS committed that all scientific notebooks would be reviewed to a standard checklist reflecting the procedural requirements for scientific notebooks. A good practice at USGS is the completion of a checklist for each scientific notebook and making the checklist a part of the notebook. Hence, the formal review, the response, and the resolution of the comments become an integral part of each scientific notebook.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions, or related additional items resulting from this audit.

5.3 QA Program Audit Activities

The Summary Table of Audit Results for Procedural Compliance Evaluations is provided in Attachment 2. The audit checklists contain the details of the audit

evaluation and the identification of the objective evidence reviewed. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Deficiencies

The audit team identified eight conditions adverse to quality. One condition adverse to quality resulted in the issuance of DR USGS-99-D-039. Two other conditions adverse to quality were referred to previously issued CAR USGS-98-C-004 and DR LVMO-98-D-055. The remaining five conditions adverse to quality required remedial action only and were corrected prior to the post-audit meeting.

A synopses of the deficiency documented on the DR, and those referred to the existing CAR and DR, and those deficiencies corrected during the audit are detailed below. The new DR has been transmitted to you under separate letter.

5.5.1 Corrective Action Requests

CAR USGS-98-C-004 was issued in December 1997 to document deficiencies regarding personnel qualifications relative to experience and education prerequisites. During this audit, an evaluation of both USGS and contractor personnel qualification records disclosed an additional example of Position Descriptions which failed to clearly depict educational and experience requirements; e.g., Position Descriptions by QAIS/PWT for administrative personnel and USGS Position Descriptions for QAISs. Additionally, an individual's qualification file included a "Letter of Attestation" that contained errors. These specifics, including personnel affected, were identified to the USGS Personnel Qualification/Training Coordinator and are documented in the completed audit checklist. A discussion was held with USGS management during this audit relative to the extent of condition and corrective action measures currently underway for this CAR. It was emphasized that this corrective action would need to address the additional example identified during this audit.

5.5.2 Deficiency Reports

USGS-99-D-039

Administrative Procedure (AP)-17.1Q, Revision 0, *Record Source Responsibilities for Inclusionary Records,* requires that "Privileged Records" be hand carried to the RPC or sent in two sealed envelopes, one within the other, with the inner envelope designating the records within as

"Privileged." Contrary to these requirements, USGS Records Transmittal Package 99.009, contained training information for nine individuals intermingled with normal processing records sent to the RPC.

LVMO-98-D-055

This DR from Audit M&O-ARC-98-06 addressed the lack of methodology for determining if Supplement V, *Control of Electronic Management of Data,* applied. Subsequently, YAP-SV.1Q, Revision 0, *Control of Electronic Management of Data,* Became effective on 2/15/99. This YAP provides direction for evaluating the adequacy of Process Controls, where the control source of information resides in an Electronic Data Management System. USGS personnel informed this audit team that Supplement V does apply to some of USGS activities, and USGS is in the process of evaluating those activities and process controls that are in place. The DR requires the revision or development of procedures as necessary and a demonstration of compliance with the procedure controls by 7/30/99.

5.5.3 Performance Reports

None

5.5.4 Deficiencies Corrected During the Audit

Deficiencies that are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. The YMPB Individual Training Assignment Form for Kristi Lewis, Quality Assurance Implementing Specialist, Pacific Western Technologies (QAIS/PWT), was filled out in 1997. However, the form was not signed by her supervisor. This form was reviewed, signed and dated by the current supervisor, Patricia Sheaffer, and annotated with the audit number and CDA.

2. There was no objective evidence that J. Golas had completed the YMP orientation prior to performing quality-affecting activities. A copy of a YMP-USGS Reading Assignment indicating that J. Golas had completed the YMP-USGS orientation on 3/25/99 was provided. The Reading Assignment was also annotated with a statement that the original YMP orientation had been obtained at a previous date and that no objective evidence could be located to substantiate attendance.

3. The USGS Receiving Report (QMP-4.01, *Procurement Document Control*, Attachment 10) for Beta Analytic, Purchase Order (PO) #98CRSA1597 Supplier Invoice was not generated as required by the

procedure. The problem appeared to be that the supplier invoices were referencing the incorrect PO number. The invoices were returned to the supplier for correction. On receipt of the corrected invoices, they were processed through without completing the Receiving Report. The Principal Investigator reviewed the invoices and completed the Receiving Report as required by the procedure during the audit.

4. During the document control evaluation, it was noted that project procedure AP 6.1Q, Revision 1, *Distribution Maintenance and Use of Controlled Documents*, was issued to supercede Affected Organizations' local procedures. USGS rescinded its YMP-USGS-QMP-6.01, Revision 7, effective 2/26/99. Two of the USGS document control procedures were found in controlled manuals during the audit. They were not marked as superceded. They were subsequently removed by appropriate personnel and the deficient condition corrected during the audit.

5. Nonconformance Report (NCR), USGS-98-007, was closed on 8/13/98. However, the "Potentially Reportable" block of this NCR form was not checked. This was corrected and a correct copy of this NCR page was transmitted to the RPC during the audit.

5.5.5 Follow-up of Previously Identified DRs:

USGS-98-D-084

USGS POs 98CRSA1597 and 99CRSA0225, Statement of Work, Section 6.0, required Beta Analytical to have a corrective action program. The Beta Analytical QA Manual, Table of Contents, Revision 2, dated 1/1/96 with updates dated 10/27/98, was reviewed by OQA and the restriction for the corrective action program and the review of procedures was removed on 11/23/98. The corrective action was determined to be effective.

USGS-98-D-116

This DR resulted from USGS Surveillance Reports, USGS-SR-98-023 and USGS-SR-98-043. The DR identified that the Scientific Notebooks failed to meet the requirements of YM-USGS-QMP-5.05. USGS committed that all Scientific Notebooks would be reviewed to a checklist comparable to the CRWMS M&O's proposed checklist. These Scientific Notebook reviews and corrections are ongoing and scheduled for completion on 5/28/99. The corrective action appears to be effective for the ongoing review process.

USGS-98-D-118

Huffman Laboratory was to be removed from the OCRWM Qualified Suppliers List (QSL) as a qualified Appendix C Supplier. Huffman Laboratory was removed from the QSL via a Supplier Evaluation Report, signed by Robert Craig on 9/28/98 and verified on 10/7/98 by OQA's Daniel Klimas. Data associated with 1997 and 1998 POs have been designated "TBV" (To Be Verified). The corrective action was determined to be effective.

6.0 Recommendations

1. It is recommended that the nine attachments to training procedure QMP 2.07, Revision 3, MOD 1, *YMP-USGS Training,* be reevaluated and eliminated or consolidated into the Attachments being used. A review of training records to the procedure disclosed that the primary means of assigning and documenting training is on forms identified in Attachments 1 and 5, while other forms; e.g., Attachment 2, are never used.

2. The YMPB Review/Comment Resolution form found in YMP-USGS-3.07, Revision 6, *YMP-USGS Review Procedure,* depicts a line at the bottom for signature and date with a comment above it that states: "I have reviewed the subject document against the criteria in the governing procedure and have determined that the document meets those criteria." While it would appear that the reviewer is expected to sign and date this after he has found the reviewed document to be acceptable, the procedure does not address this. An evaluation of a number of reviews during the audit disclosed that, while most reviewers signed and dated this statement *after* acceptance of all comment resolutions, some reviewers signed this block at the initial time of making their comments and prior to them being resolved. It is recommended that the procedure be clarified to address when this signature block is to be completed.

3. During the USGS audit relative to procedures, it was noted that procedure YMP-USGS-QMP-5.01, Revision 8, *Preparation of Technical Procedures,* lacked clarity in some areas, was implicit rather than explicit relative to some QARD requirements and overall could be improved. It is recommended that this procedure should be revised to address the following:

   - Paragraph 5.3.1 titled, "REVIEW CRITERIA," is intended to depict the criteria used by OQA in a review of technical procedures. However, the only criteria cited is to ensure "adequate and appropriate QA controls." This is not objective explicit criteria. The USGS OQA representatives utilize a detailed criteria checklist (developed informally) that clearly depicts substantive review criteria in all of their procedure reviews. The criteria in these checklists need to be incorporated into the procedure.

- While the necessary approvals are described, procedure YMP-USGS-QMP-5.01, Revision 8, does not clearly detail how "expedited changes" are to be processed and documented; i.e., what format is used? How are they documented? The expedited change process in companion procedure YMP-USGS-QMP-5.03, Revision 10, *Development and Maintenance of Quality Management Procedures*, clearly identifies a Modification form called a "Mod" (Attachment 1 to the procedure). QMPs with outstanding Mods to them are controlled as M1, M2, M3, etc. to the procedure. While document control also shows an M1, M2, M3 to technical procedures, YMP-USGS-QMP-5.01, Revision 8, does not address the expedited change as a Mod nor define how this change is depicted; i.e., with an "M." It is recommended that the expedited change process in YMP-USGS-QMP-5.01, Revision 8, be revised to be consistent with the one depicted in YMP-USGS-QMP-5.03, Revision 10.

4. Clarification to both YMP-USGS-QMP-5.01, Revision 8, and YMP-USGS-QMP-5.03, Revision 10, should be considered relative to the following:

   The QARD requires that when work cannot be performed to a procedure as written, that the work be stopped until a procedure is revised or replaced. Neither YMP-USGS-QMP-5.01, nor YMP-USGS-QMP-5.03 have an explicit requirement to *stop* work until a procedure is revised or replaced. The Expedited Change process in YMP-USGS-QMP-5.01, Revision 8, implies that work is stopped when a procedural change is necessary due to schedule impacts or a change is necessary. YMP-USGS-QMP-5.03, Revision 10, does not address stopping work when the procedure cannot be followed anywhere. Both of these procedures should be revised to fully clarify how work is controlled.

5. It is recommended that the unique control number assigned to controlled document holders be identified on the controlled documents in their possession. This recommendation was made during the last audit of USGS. Subsequent to that audit, project procedure AP 6.1Q which requires this to be done became effective. It was observed that USGS was only identifying this number on documents issued after the effective date of the AP and not on documents previously issued. After some discussion, USGS agreed to put these numbers on previously issued documents that are current.

6. It is recommended that, for the initial calibration of a new instrument, the Certification of Calibration be annotated with the phrase, "Initial Calibration." In several instances the instrument as received by the calibration facility indicated the instrument was out-of-tolerance. This raises questions and without the USGS database "Querallmar" history, you are unable to determine if it is actually the initial calibration.

7. It is recommended that the USGS calibration files at the Hydrologic Research Facility (HRF) be separated into "Active" and "Suspended" files. Currently the files are inter-mixed. The HRF instrument database separates the active and out-of-service instruments. However, for consistency and to avoid confusion, the files should be separated.

8. There are two NCRs (USGS-95-0011 and USGS-97-0009) that have been open for over two years (with several others over one year old). In the spirit of timely corrective action, it is recommended that immediate and necessary resources be provided to bring these NCRS to resolution.

9. Scientific notebook SN-105, *Tracer Test,* an ancillary notebook contained the strip charts for the recorded data. However, the conversion of the strip chart data to the recorded data in the scientific notebook was not readily apparent. The recommendation is to describe the process to convert this strip chart information to the values recorded in the scientific notebook.

7.0 List of Attachments

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results for Procedural Compliance Evaluations

ATTACHMENT 1

Personnel Contacted During the Audit
Las Vegas

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Anderson, A.	Secretary, EAG		X	
Anna, L.	Hydrology and Climate/UZ		X	
Brady, T.	ESIP Technical Publication		X	
Chaney, T.	Chief, EA, USGS	X	X	X
Craig, R.	Technical Project Officer, USGS		X	
Ducret, L.	Chief, Planning and Support Program		X	
Golos, J.	Operations Specialist, USGS		X	X
Graves, R.	Principal Investigator		X	
Guertal, W.	Hydrologist, USGS		X	
Hersh, B.	EA Procurement USGS/PWT	X	X	X
Hommel, D.	Hydro/Cal Technician		X	
Jeffery, P.	Administrative Operations (Matrixed)		X	
Jordan, J.	QAIS (PWT)		X	
Kurzmack, M.	Senior Scientifist		X	
Larsen, K.	Tech.Data Management .Specialist, USGS/PWT	X		
Lewis, K.	QAIS – Pacific Western Technology (PWT)	X	X	X
Lykins, A.	QA Specialist, USGS		X	
Marshall, B.	Hydrologist, USGS		X	
McKinley, P.	Data Coordinator	X	X	X
Miller-Corbert, C.	Hydrologist Software, USGS			X
Murry, M.	Administrative Assistant		X	
Mustard, M.	Hydrologist (EA) USGS	X	X	X
Nelson, M.	Administrative Operations		X	X
Oliver, T	Hydrologist		X	
Paces, J.	Hydrologist, USGS		X	
Parks, B.	Associate Chief, ESIP, USGS		X	X
Patterson, G.	Principal Investigator		X	
Rimes, D.	Hydrologist, USGS		X	
Scofield, K.	Hydro Technician, USGS		X	
Severson, Gary	Principal Investigator		X	
Sheaffer, P.	QAIS (PWT)		X	
Sinks, D.	Quality Assurance Specialist, OQA/QATSS – USGS	X	X	X
Striffler, P.	Hydrologist, USGS		X	
Whiteside, A.	Quality Assurance Specialist, OQA/QATSS – USGS	X	X	X

ATTACHMENT 2
Summary Table of Audit Results
For Procedural Compliance Evaluations

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (CHECKLIST)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1	DOE/RW-0333P, Rev. 8	Pgs. 1, 5, 6	N	N	SAT	SAT	SAT
	YMP-USGS-QMP-1.01, Rev. 6/MOD 1	Pgs. 2-4	N	N	SAT	SAT	
2	YMP-USGS-QMP-3.07, Rev. 6	Pgs. 7-10	N	REC #2	SAT	SAT	SAT
	QMP-2.02, Rev. 7	Pgs. 11-13	USGS-98-C-004 CDAs #1 & #2	N	SAT	UNSAT	
	QMP-2.08, Rev. 3	Pgs. 14-18	N	N	SAT	SAT	
	QMP-2.07, Rev. 3/MOD 1	Pgs. 19-24	N	REC. #1	SAT	SAT	
4	USGS-QMP-4.01, Rev. 9, MOD 2	Pgs. 25-29	CDA #3	N	SAT	SAT	SAT
	USGS-QMP-4.02, Rev. 7	Pgs. 30-33	N	N	SAT	SAT	
5	YMP-USGS-QMP-5.01, Rev. 8	Pgs. 34-37 Pgs. 42-44	N	RECs #3 & #4	SAT	SAT	SAT
	YMP-USGS-QMP-5.03, Rev. 9/MOD 1	Pgs. 44-47	N	RECs #4 & #5	SAT	SAT	
6	YMP-USGS-QMP-6.01, Rev. 7	Pgs. 38-41	CDA #4	REC. #3	SAT	SAT	SAT
7	AP-7.4Q, Rev. 3	Pgs. 48-49	N	N	SAT	SAT	SAT
12	USGS-QMP-12.01, Rev. 8/ MOD 1	Pgs. 50-57	N	RECs #6 & #7	SAT	SAT	SAT
15	YAP-15.1Q, Rev. 4	Pgs. 58-60	CDA #5	REC #8	SAT	SAT	SAT

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (CHECKLIST)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
16	AP-16.1Q, Rev. 3	Pg. 61	N	N	SAT	SAT	SAT
	AP-16.2Q, Rev. 2	Pg. 62	N	REC. #5	SAT	SAT	
	AP-16.4Q, Rev. 0	Pg. 63	N	N	SAT	SAT	
17	AP-17.1Q, Rev. 0/ICN 1	Pgs. 64-70	USGS-99-D-039	N	SAT	UNSAT	SAT
SI	YMP-USGS QMP-3.03, Rev. 7/MOD 1	Pgs. 71-79	N	N	SAT	SAT	SAT
SII	YMP-USGS QMP-8.01, Rev. 4, MOD 1	Pgs. 84-86	N	N	SAT	SAT	SAT
	YAP-SII.4Q, Rev.2	Pgs. 80-83	N	N	SAT	SAT	
SIII	USGS-QMP-5.05, Rev. 6	Pg. 91	N	REC #9	SAT	SAT	SAT
	USGS-QMP-3.04, Rev. 9	Pgs. 87-90	N	N	SAT	SAT	
	USGS-QMP-3.16, Rev. 0/ MOD 1	Pg. 92	N	N	NI	NI	
SV	YAP-SV.1Q, Rev. 0	Pgs. 93-94	LVMO-98-D-055	N	NI	NI	NI
TOTAL		**Pgs. 94**	**5 CDAs 1 New DR 1 Previously issued CAR 1 Previously issued DR**	**9 RECs**	**SAT**	**SAT**	**SAT**

LEGEND:

N……. None
NI…… Not Implemented
SAT…… Satisfactory
CDA…… Corrected During Audit
REC…… Recommendation